UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

MEDWIN FAMILY MEDICINE AND REHABILITATION, P.L.L.C., Plaintiff,	§	
v.	§	Case No. 1:15-cv-151
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, Defendant.	§	

MAGISTRATE JUDGE'S
REPORT AND RECOMMENDATION

Plaintiff Medwin Family Medicine and Rehabilitation, P.L.L.C. (hereinafter referred to as "Medwin") has filed a Motion for Summary Judgment in this civil action. Dkt. No. 24. Defendant Sylvia Mathews Burwell, Secretary of the United States Department of Health and Human Services (hereinafter, "the Secretary") has filed a Cross Motion for Summary Judgment. Dkt. No. 27. After full consideration of both Motions for Summary Judgment and all related submissions, it is recommended that the Court: (1) grant the Secretary's Cross Motion for Summary Judgment; (2) deny Medwin's Motion for Summary Judgment; and, (3) dismiss this civil action with prejudice.

I. Background, Jurisdiction and Venue

This civil action arises under the Medicare Act, which is codified at 42 U.S.C. § 1395 et seq. The Medicare Act is part of Title XVIII of the Social Security Act.

Baylor Univ. Med. Ctr. v. Heckler, 730 F.2d 391, 391 (5th Cir. 1984) (per curiam). The Medicare Act was established to provide health insurance to the elderly and disabled. *D&G Holdings, LLC v. Sylvia Mathews Burwell*, 156 F. Supp. 3d 798, 805 (W.D. La. 2016) (citing 42 U.S.C. §§ 1395-1395lll). The Medicare Act is composed of Parts A, B, C, D, and E. 42 U.S.C. § 1395 et seq. This civil action concerns Part B. *See* Dkt. No. 1 at ¶ 18; Dkt. No. 27 at 2.

Part B of the Medicare program provides voluntary, supplemental medical insurance. 42 U.S.C. § 1395j. It covers "medical and other health-care services," including "diagnostic tests[.]" *Id.* at § 1395k(a)(1), and § 1395x(s)(3). The Secretary administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). *Arkansas Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006); *Miracle Care Hospice, Inc. v. Sebelius*, No. 3:12-CV-495-CWR-FKB, 2014 WL 1324279, at *1 (S.D. Miss. Mar. 31, 2014) (same). Through CMS, the Secretary utilizes Medicare contractors to assist with Part B claim determinations. 42 U.S.C. § 1395u.

Medwin is a provider of healthcare services to Medicare beneficiaries under Part B. Dkt. No. 1 at ¶ 7; Dkt. No. 17 at ¶ 7. Medwin's principal office is located in Brownsville, Texas. Dkt. No. 1 at ¶ 5.[1] As part of its services, Medwin provides electrodiagnostic studies to help diagnose and treat its patients. *Id.* at ¶ 17. Medwin performed electrodiagnostic studies on six Medicare patients in 2012. *Id.* at ¶ 1, 19.

[1] As the Secretary agrees that the material facts of this case are undisputed (*see* Dkt. No. 22 at 1; Dkt. No. 27 at 2), the Court recites material facts primarily from Medwin's pleadings.

Specifically, Medwin performed various sensory and nerve conduction tests for patients presenting with symptoms of radiculopathy/sciatica. *Id*. at ¶ 25.[2]

Medicare paid Medwin's claims for these tests initially. Dkt. No. 1 at ¶ 26. Later, however, a Medicare contractor, Novitas Solutions, Inc., ("Novitas"), determined that Medicare had overpaid Medwin and sought to recoup the payments. *Id*. Medwin proceeded to appeal this decision administratively. *Id*. at ¶¶ 20-22. On June 24, 2015, the Medicare Appeals Council (hereinafter, the "Council") entered a final decision denying Medwin's appeal. According to the Council, Medwin was overpaid in the amount of $585.32 for each of the six patients at issue. Administrative Record ("AR") at 14, 194-210, 1000-1008.[3] Medwin seeks judicial review of the Council's decision. Dkt. No. 1 at ¶ 1.

The parties agree that, pursuant to 42 U.S.C. § 405.1136(d), the Secretary is the proper defendant in this action as the adopter and issuer of final decisions made by the Council. Dkt. No. 1 at ¶¶ 4 and 6; Dkt. No. 17 at ¶¶ 4 and 6. The parties additionally agree that Medwin's Original Complaint is timely, the amount in controversy is satisfied, and all conditions precedent to filing suit have been met. Dkt. No. 1 at ¶¶ 4, 6, 15; Dkt. No. 17 at ¶¶ 4, 6, 15. Jurisdiction and venue are not disputed. Dkt. No. 1 at ¶ 4; Dkt. No. 17 at ¶ 4. The Court finds that: (1) the Secretary

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[2] As relevant in this case, radiculopathy and sciatica are synonymous terms. *See* Dkt. No. 27-7 at 26 (referring to "Radiculopathy (i.e., sciatica)"). *See also* Dkt. No. 27 at 9, note 6 ("*Sciatica*, also known as lumbar radiculopathy, is a pain that originates along the sciatic nerve, which extends from the back of the pelvis down the back of the thigh. Johns Hopkins Health Library: www.hopkinsmedicine.org/healthlibrary/conditions/spine_shoulder_and_Pelvis_disorders/sciatica_85,p01382/).

[3] The Court will cite the Administrative Record according to its page numbers 1-1260, as both parties have done in their pleadings.

is the proper defendant in this action; (2) Medwin's Original Complaint is timely; (3) the amount in controversy is satisfied; (4) all conditions precedent have been met; (5) jurisdiction and venue are proper; and, (6) this Court may review the Council's June 24, 2015 decision as the Secretary's final, appealable decision. *See* 42 U.S.C. § 405(g), § 405.1006(c), § 405.1130, § 405.1136; § 1395ff(b). *See also* AR at 3 (containing the Council's explanation of the requirements for judicial review of its decision).

II. Legal Standards

A. FED. R. CIV. P. 56. The standard applied when ruling on a motion for summary judgment is set forth in Rule 56 of the Federal Rules of Civil Procedure. FED. R. CIV. P. 56(a). In pertinent part, Rule 56 provides that the court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Id.*, *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 2552 (1986) (same). Mere allegations of a factual dispute between the parties will not defeat an otherwise proper motion for summary judgment. Rule 56 requires that there be no genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

A fact is material if it might affect the outcome of the lawsuit under the governing law. *Anderson*, 477 U.S. 242, 248. A dispute about a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* Therefore, summary judgment is proper if, under governing laws, there is only one reasonable conclusion as to the verdict. If reasonable finders of

fact could resolve a factual issue in favor of either party, summary judgment should not be granted. *Id*. at 249.

The movant on a summary judgment motion bears the initial burden of providing the court with a legal basis for its motion and identifying those portions of the record which demonstrate the absence of a genuine issue of material fact. The burden then shifts to the resisting party to present affirmative evidence to defeat the motion. *Anderson*, 477 U.S. 242, 257. All facts and inferences drawn from those facts must be viewed in the light favorable to the party resisting the motion for summary judgment. *Scott v. Harris*, 550 U.S. 372, 378 (2007). "The court need consider only the cited materials, but it may consider other materials in the record." FED. R. CIV. P. 56(c)(3).

B. The Court's Review of the Secretary's Decision. In *Girling Health Care, Inc. v. Shalala*, the Fifth Circuit noted:

> The summary judgment procedure is particularly appropriate in cases in which the court is asked to review or enforce a decision of a federal administrative agency. The explanation for this lies in the relationship between the summary judgment standard of no genuine issue as to any material fact and the nature of judicial review of administrative decisions. . . . [T]he administrative agency is the fact finder. Judicial review has the function of determining whether the administrative action is consistent with the law—that and no more.

Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 214–15 (5th Cir. 1996) (alterations in original) (quoting 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure: Civil 2d § 2733 (1983)). Section 1395ff(b) of Title 42 provides that any individual dissatisfied with the Secretary's final decision regarding

a claim may obtain judicial review as provided in 42 U.S.C. § 405(g). 42 U.S.C. § 1395ff(b).

Where § 405(g) governs, review of the Secretary's decision is limited to two inquiries: (1) whether the Secretary applied the correct legal standards; and (2) whether there is substantial evidence in the record to support the Secretary's decision. *Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (citing *Paul v. Shalala*, 29 F.3d 208, 210 (5th Cir. 1994) and *Anthony v. Sullivan*, 954 F.2d 289, 292 (5th Cir. 1992)); *Maxmed Healthcare, Inc., v. Burwell*, 152 F.Supp.3d 619, 625 (W.D. Tex. 2016) (same). When considering whether the Secretary applied correct legal standards, courts are required to give "substantial deference" to her interpretation of Medicare's regulations. *Maxmed Healthcare, Inc.*, 152 F.Supp.3d 619, 625 (citing *Girling Health Care*, 85 F.3d at 215). When considering whether substantial evidence exists to support the Secretary's decision, courts must be mindful that substantial evidence is more than a mere scintilla. *Id*. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id*. (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971) and *Consol. Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229 (1938)). The reviewing court "'may neither reweigh the evidence in the record nor substitute [its own] judgment for the Secretary's.'" *Id*. (quoting *Hollis v. Bowen*, 837 F.2d 1378, 1383 (5th Cir. 1988)).

Despite the longstanding existence of the above-discussed standard of review, Medwin argues that that the Fifth Circuit has "issued conflicting opinions regarding the appropriate standard of review." Dkt. No. 24 at 10.

> In *Estate of Morris*, the Court rejected a party's contention that the Administrative Procedure Act ("APA") provided the standard of review. 207 F.3d at 745. However, in *Texas Clinical Laboratories, Inc. v. Sebelius*, the Court cited the APA without any expression of doubt. 612 F.3d 771, 775 (5th Cir. 2010) ("Under the Administrative Procedures Act ("APA"), "[t]he district court, and this court . . . may overturn the Secretary's ruling only if it is arbitrary, capricious, an abuse of discretion, not in accordance with law, or unsupported by substantial evidence on the record taken as a whole.") (quoting *Sun Towers, Inc. v. Schweiker* (*Sun Towers I*), 694 F.2d 1036, 1038 (5th Cir. 1983)).

Id. (errors in original).

Medwin argues that the Court should follow *Texas Clinical Laboratories*, and apply the "arbitrary and capricious" APA standard for three main reasons. Dkt. No. 24 at 10-12; Dkt. No. 32 at 2-4. First, Medwin argues that *Texas Clinical Laboratories* is the most recent pronouncement of the standard of review and "at least one court in this district has followed it." Dkt. No. 24 at 10 (citing *Transyd Enters., L.L.C. v. Sebelius*, No. M–09–292, 2012 WL 1067561 (S.D. Tex. Mar. 27, 2012)). Second, Medwin states that other circuits, and courts within those circuits, apply the APA standard. *Id.* at 11-12; Dkt. No. 32 at 3-4. Third, Medwin asserts that the § 405(g) standard provides "for a substantial evidence review, but little more." Dkt. No. 24 at 11. Medwin indicates that § 405(g) should be supplemented by the APA standard because the APA "'sets forth the full extent of judicial authority to review executive agency action for procedural correctness.'" *Id.* at 11-12 (citing "*FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009); *Gentiva Healthcare Corp. v. Sebelius*, 857 F. Supp. 2d 1, 6 (D.C. Dist. Apr. 6, 2012)). Medwin claims that the cases it relies upon should be followed by this Court because they concern Medicare debts, and/or

interpret provisions within the Social Security Act. Dkt. No. 24 at 10-12; Dkt. No. 32 at 2-4.

In her Response in Opposition to Plaintiff's Motion for Summary Judgment (hereinafter, the Secretary's "Response"), the Secretary states that Medwin's claim, that the arbitrary and capricious standard applies here, is incorrect. Dkt. No. 31 at 2, note 1. The Secretary notes that Medwin is relying upon "cases that apply the standard of review articulated in non-Social Security appeals." *Id.* The Secretary avers that Medwin brought this action pursuant to 42 U.S.C. § 1395ff(b)(1)(A), "which incorporates the standards and procedures of 42 U.S.C. § 405(g), i.e., the "substantial evidence" standard. *Id.*[4]

The Secretary's argument is supported by binding Fifth Circuit authority. In *Estate of Morris v. Shalala*, the Fifth Circuit addressed the plaintiff's argument that the APA standard of review was the correct standard of review. The Fifth Circuit explained that this was not accurate.

> Notwithstanding these authorities, Morris contends that the standard of review is found in the Administrative Procedure Act ("APA"). But the estate cites *Hennepin County Medical Center v. Shalala*, 81 F.3d 743 (8th Cir. 1996), which did not arise from an individual's appeal of a Secretary's denial of benefits under 42 U.S.C. § 1395ff(b). *Hennepin* instead involved a provider's appeal under 42 U.S.C. § 1395oo(f)(1) for reimbursement of unrecovered expenses incurred by Medicare patients. As § 1395oo(f)(1) does not incorporate § 405(g), *Hennepin* is inapposite. The § 405(g) standard controls.

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[4] The Secretary's response is somewhat inconsistent with an earlier representation to this Court. In the parties' Joint Statement of Undisputed Facts, both parties appear to suggest that the APA standard of review applies, along with the § 405(g) standard of review. Dkt. No. 22 at 1-2. Nevertheless, this case does not turn on whether the APA standard of review applies. For the reasons provided below, Medwin has not demonstrated that the Secretary abused its discretion or otherwise acted arbitrarily or capriciously because Medwin has not shown that the Secretary erred in the first instance.

Estate of Morris v. Shalala, 207 F.3d 744, 745 (footnote omitted).

Like the plaintiff in *Estate of Morris*, Medwin primarily relies upon cases that were not brought pursuant to 42 U.S.C. § 1395ff(b). *See* Dkt. No. 24 at 10-12; Dkt. No. 32 at 2-4. *Texas Clinical Laboratories,* for example, was not brought pursuant to 42 U.S.C. § 1395ff(b), and is distinguishable from *Estate of Morris*. Having failed to cite any on-point Fifth Circuit or Supreme Court authority displacing *Estate of Morris*, this Court finds that Medwin has failed to show that the APA standard of review is applicable here. Accordingly, the applicable standard of review is the standard provided in 42 U.S.C. § 405(g). *See Estate of Morris v. Shalala*, 207 F.3d 744, 745 (rejecting the application of the APA standard, and applying 42 U.S.C. § 405(g)); *United Medical Healthcare, Inc. v. Department of Health and Human Services*, 889 F. Supp. 2d 832, 839–40 (E.D. La., 2012) (same).

III. Medwin's Claims and the Secretary's Procedures, Requirements, and Decisions

With respect to the six patients at issue, Medwin claims that it was underpaid, rather than overpaid, for its services. Dkt. No. 1 at ¶ 26. Medwin additionally argues that it exercised reasonable care in billing and accepting payment from Medicare for its services. *Id*. at ¶ 34. Because it exercised reasonable care, Medwin states that it should be considered "'without fault' for any overpayment" pursuant to 42 U.S.C. § 1395gg(b). *Id*. Medwin contends that the alleged overpayments were wrongfully recouped. Therefore, Medwin should be reimbursed, with interest, along with its court costs and attorneys' fees. *Id*. at ¶¶ 26, 49.

As will be made clear below, reviewing the merits of Medwin's allegations requires an understanding of Medicare's procedures and requirements, along with the Secretary's decisions in this particular case. Accordingly, before examining Medwin's claims, the Court will briefly describe Medicare's relevant procedures and requirements, in conjunction with the Secretary's decisions.

A. Medicare's Administrative Procedures and Requirements. Medicare contractors make the initial determination on claims submitted under Part B by applying the Secretary's policies and regulations. 42 U.S.C. § 1395ff(a)(1); *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F.Supp.2d 98, 104 (D. Mass. 2009).[5] The policies and regulations involved in determining Medicare claims are varied and somewhat complex.

> In making coverage decisions, Medicare contractors rely on regulations promulgated by HHS, as well as on National Coverage Determinations ("NCDs")—made by CMS—and Local Coverage Determinations ("LCDs")—made by [local Medicare contractors]. The Secretary adopts NCDs to exclude certain items and services from coverage on a national level that are not "reasonable and necessary" under the agency's interpretation of the Medicare statute. *See* 42 U.S.C. § 1395ff(f)(1)(B). These determinations are binding on all Medicare contractors nationwide. When no NCD applies to a claim, Medicare contractors must still apply the "reasonable and necessary" limitations in LCDs in determining whether to pay a claim and in what amount. . . . Although "reasonable and necessary" is not defined in the Medicare statute, Congress has vested final authority in the Secretary to determine what items or services are "reasonable and necessary." *See* 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984). In accordance with this authority, the Secretary has promulgated regulations relating to the "reasonable and necessary" requirement. CMS has also issued NCDs specifying conditions for Medicare coverage of certain items and services. Finally, contractors have also issued LCDs and policy guidance to address local coverage issues.

[5] The contractors are usually private insurance companies or other independent entities. 42 U.S.C. § 1395kk-1; *Willowood of Great Barrington, Inc.*, 638 F.Supp.2d 98, 104.

C & I Medical Equipment and Supplies, Inc. v. Sebelius, 2010 WL 2376165, at *1 (E.D. Mich., 2010) (formatting altered).

If a provider of Medicare services wishes to appeal a Medicare contractor's initial determination, they must proceed through the following five steps:

> **1. Redetermination**. A redetermination is an examination of the initial claim decision. 42 C.F.R. § 405.940 et seq.
>
> **2. Reconsideration**. A reconsideration is an independent review performed by a Qualified Independent Contractor (QIC). 42 C.F.R. § 405.960 et seq.
>
> **3. Administrative Law Judge (ALJ) Hearing**. If the minimum amount of controversy is met, a hearing before an ALJ may be requested. 42 C.F.R. §§ 1002(a)(2), 405.1006(b).
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> > When an appellant requests escalation of a case to the Council without ALJ action, and procedural requirements are met, "the QIC decision becomes the decision that is subject to Council review consistent with 405.1102(a)." 42 C.F.R. § 405.1108(a). The Council reviews the QIC reconsideration *de novo*. *Id*. The Council may adopt, modify, or reverse the QIC reconsideration or remand the case to an ALJ for further proceedings. *Id*. The Council may also dismiss the request for escalation because the appellant does not have the right to escalate the appeal. *Id*. § 405.1108(d)(4). The Council may also dismiss the request for a hearing for any reason that the ALJ could have dismissed the request. *Id*. § 405.1108(d)(5).
>
> **4. Medicare Appeals Council Review**. If a provider or beneficiary is dissatisfied with an ALJ decision, they may request review by the Council. 42 C.F.R. § 405.1102(a). The Council may also decide on its own motion to review a decision of the ALJ. 42 C.F.R. § 405.1110.
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> **5. Judicial Review in a United States District Court**. Judicial review of the Council's decision may be requested within 60 days of the decision, if the minimum amount remaining in controversy is met. 42 U.S.C. § 1395ff(b)(1)(E); 42 C.F.R. § 405.1136; 42 C.F.R. § 405.1130.

Dkt. No. 27 at 8-9 (formatting altered). *See also* Dkt. No. 24 at 8-10 (same).[6]

B. The Secretary's Decisions. Medicare contractor Novitas made the initial determinations that Medicare had overpaid Medwin in all six cases. AR at 194, 1000. The parties agree that Medwin followed the above-described process in appealing Novitas's decisions. Dkt. No. 1 at ¶¶ 9-14; Dkt. No. 17 at ¶¶ 9-14. At step one, Novitas granted Medwin's requests for a redetermination, but declined to alter its decisions. At step two, the QIC granted Medwin's requests for reconsideration, but affirmed Notivas's decisions. At step three, Medwin sought a hearing before an ALJ. Because there was a backlog of cases before the ALJ, Medwin escalated its appeal and sought review before the Council. At step four, the Council affirmed the QIC's reconsideration decisions in all six cases. Pursuant to step five, Medwin filed its Original Complaint in this District Court. *Id*.

The parties agree that, in each of the six cases, the Council found that Medwin had performed diagnostic tests that were not medically reasonable and necessary. Dkt. No. 1 at ¶¶ 28-30; Dkt. No. 17 at ¶¶ 28-30. More specifically, the Council found that Medwin conducted "additional motor and nerve sensory tests beyond what the Utilization Guidelines chart in the LCD L26776" indicated "were necessary to treat each specific beneficiary's condition." AR at 12.

Again, an LCD is a "Local Coverage Determination." *C & I Medical Equipment and Supplies, Inc. v. Sebelius*, 2010 WL 2376165, at *1. LCD L26776 pertains to "Electrodiagnostic Studies (NCS/EMG)." Dkt. No. 27-7 at 2. LCD L26776 contains "Utilization Guidelines" which list the number of diagnostic tests allowed under

[6] Both parties describe this five-step procedure in their briefing, although Medwin's description is more detailed. Dkt. No. 27 at 8-9; Dkt. No. 24 at 8-10.

Medicare per patient, per year, along with the number of tests allowed per diagnosis. *Id.* at 21-22, 26. Pursuant to the Health Care Financing Administration Common Procedure Coding System ("HCPCS"), each test is identified by a code. AR at 4, note 1. The HCPCS incorporates codes from the American Medical Association's Current Procedural Terminology ("CPT") Manual. *Id.* *See also Svidler v. U.S. Dept. of Health and Human Services*, 2004 WL 2005781, at *3 n.1 (N.D. Cal., 2004) ("The procedural system utilized by Medicare for billing is the Health Care Financing Administration Common Procedure Coding System (HCPCS). It is based upon the American Medical Association's Physicians' Current Procedural Terminology manual, Fourth Edition (CPT–4)[.]").[7]

The Utilization Guidelines found in LCD L26776 provide codes for diagnostic tests, along with a corresponding number for each test, which represents the number of tests allowed per patient, per year. Dkt. No. 27-7 at 21-22. For the tests at issue in this case, tests coded as tests "95903" and "95904,"[8] the LCD L26776 Utilization Guidelines provide for eight tests per year, per patient for test 95903, and ten tests per year, per patient for test 95904. *Id.* Relatedly, LCD L26776 contains a Utilization Guideline Table which provides that a radiculopathy/sciatica diagnosis may generally

[7] The CPT Manual, "contains a listing of descriptive terms and identifying code numbers for the standardized reporting of approximately 7,500 medical services and procedures performed by physicians. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services to facilitate nationwide communications among health care workers, patients, and others." *American Soc. of Dermatology v. Shalala*, 962 F.Supp. 141, 144 (D.D.C., 1996) (citations omitted).

[8] *See* AR at 4 (noting that the six cases at issue concern Part B coverage of tests coded as 95903 and 95904); *see also* Dkt. No. 1 at 5-6 (same), and Dkt. No. 27 at 2 (same).

be established by performing no more than two 95903 "F-Wave" tests, and two 95904 "Sensory NCV" tests. Dkt. No. 27-7 at 26.

In adopting the QIC's reconsideration decision in the six cases, the Council made several findings and observations. In relevant part, those findings and observations are as follows:

> In each instance, the QIC determined that [Medwin] performed additional motor and nerve sensory tests beyond what the Utilization Chart in the LCD indicated were necessary to treat each specific beneficiary's condition. The LCD allows for coverage of additional testing if an appellant provides medical documentation supporting the need for the extra testing. [Medwin] has not done so in this case.
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> . . . . [Medwin's] hearing request [before the ALJ] did not address the specific denial reason in the QIC reconsiderations, *i.e.* that [Medwin] billed additional units of 95904 and 95903 without providing medical documentation supporting the need for the extra testing.
>
> Before the Council, in its supplemental briefing, [Medwin] has now addressed the specific denial basis of the QIC's reconsideration decisions for each beneficiary. Exh. MAC-3. [Medwin] contends that under the LCD, "8 tests under CPT 95903 and 10 tests under CPT 95904" may be billed per year per patient. *Id*. Further, [Medwin] asserts that, per the medical records, the total of four sensory nerve conduction studies and four motor nerve conduction studies were medically necessary. *See* Exh. MAC-3 (referring to beneficiary M.V.). [Medwin] attached medical records which were previously sent to the QIC as well as an updated letter of medical necessity dated May 29, 2015. *Id*.
>
> [Medwin] is correct that the body of the LCD contains per year limits. However, [Medwin] did not acknowledge or submit the Utilization Chart (or Table) attached to the LCD which establishes limits on the number of tests deemed medically reasonable and necessary to evaluate certain diagnoses. The Council does not find that [Medwin] has adequately documented the need for testing additional sites greater than the numbers indicated in the Utilization Chart attached to LCD L26776. First, [Medwin] relies on language in the LCD allowing 8 and 10 tests per patient per year. *See* LCD L26776; *see also* Exh. MAC-3. The QIC did not deny the claims on the basis that [Medwin] billed more test in a year than is allowed. Instead, the QIC's denial is based on the numbers of sites tested, on a particular date of service, for a specific diagnosis. *See*

> *e.g.*, MV File, Exh. 6 at 7. Therefore, the total number of tests allowed per year is not relevant in this case.
>
> The attachment to the LCD is clear, however, as to the maximum number of sites that may be billed to Medicare for the 95904 and 95903 codes on a particular date of service and diagnosis. In each instance, for a diagnosis of sciatica, [Medwin] exceeded the maximum number of tests needed to diagnose each beneficiary's condition. *See* LCD L26776. The medical records provided by [Medwin] do not explain why the additional testing was medically necessary. Exh. MAC-3.

AR at 12-13 (errors in original).

C. Medwin's Claims. Before this Court, Medwin disputes the Council's finding that it failed to show that the contested, additional tests were medically necessary to diagnose the conditions of the six patients. Dkt. No. 1 at ¶ 33. It argues that the six patients, M.V., R.F., E.P., D.V., J.A., and R.M.,[9] were all being evaluated for the same condition, radiculopathy. Dkt. No. 24 at 15. Despite this, Medwin argues that for four patients, "the Agency determined that 3 motor nerves should be tested[,]" while for "one of the patients the Agency determined that 4 motor nerves should be tested." *Id*. Medwin contends that the QIC "randomly issues favorable and unfavorable decisions based on nearly identical claims for identical services, but with incoherent rationales." *Id*. at 19.

Medwin adds that, the Council found that only "2 sensory NCS" tests where necessary to diagnose its patients, but that Medwin did the two sensory NCS tests bilaterally because it was medically necessary. Dkt. No. 24 at 15. Medwin contends the Council's "denial of claims for bilateral testing is unsupported by substantial evidence in the record." *Id*. Medwin states that its billing was also proper because the

[9] The six patients at issue in this case are referred to by their initials only to protect their privacy.

Utilization Guidelines in LCD L26776 provide for "8 sensory NCS (95903)" tests per year, and "10 motor NCS (95904)" tests per year. *Id*. It argues that its claims should not have been denied on the grounds that it tested excessively, because it provided "medical documentation supporting the testing[.]" Dkt. No. 30 at 4.

Next, Medwin claims that the Court should consider the Secretary's decisions approving Medwin's claims for some of its other patients, even though those patients' claims are not at issue in this case. Dkt. No. 24 at 16-19. Medwin argues that this is appropriate because it merely involves "completing" the record with relevant evidence that was directly or indirectly before the Secretary's agents. *Id*. at 16-18. In the alternative, Medwin contends that it should be permitted to "supplement" the record in this case with the records of its other patients' claims. *Id*. at 18-19. Medwin states that doing so will allow the Court to see that the Secretary applies LCD L26776 randomly, and in an arbitrary and capricious manner. *Id*. at 16-19.

With respect to these other patients, Medwin argues that the QIC has paid claims for "additional units of sensory and nerve conduction studies based on documentation that was similar" to the documentation submitted in the six cases at issue here. Dkt. No. 1 at ¶ 33. Medwin correctly points out that its appeal to the Council originally involved eight beneficiaries. Dkt. No. 24 at 17. On appeal before the Council, Medwin "prevailed on testing done to two beneficiaries by obtaining a favorable reconsideration by the QIC." *Id*. Medwin argues that, when comparing the QIC's decision in the two beneficiaries cases with the QIC's decision in the six cases at issue here, it is clear that "the reasons for the favorable and unfavorable

reconsiderations by the OIC [sic] are ***nearly identical***." *Id.* at 17 (emphasis in original).

Relatedly, Medwin relies upon the records of patient "M.G.", a patient whose claim was paid. Dkt. No. 24 at 15-16.[10]

> [Medwin] refers to the appeal relating to M.G. AR 001208 and 001213. The claim was originally denied by Novitas, but the Qualified Independent Contractor, Q2 Administrators, determined that the claim was not overpaid. *See* Exhibit 1. Furthermore, the QIC determined that the LCD requirements had been met. *Id.* That same QIC denied claims for the same testing and for the same indication in the appeals made the basis of this lawsuit. The decision to deny claims after having determined similar claims are payable is an abuse of discretion, arbitrary and capricious.

Id. at 16 (errors in original). *See also* Dkt. No. 32 (making the same argument, but referring to the patient inconsistently as "M.D." and "M.G."). Medwin's Motion for Summary Judgment concludes by stating that the Secretary has applied the LCD and documentation requirements randomly, and that the Secretary has "abused its discretion in denying some claims after having concluded that other identical claims meet the LCD and Medicare reimbursement requirements." Dkt. No. 24 at 19.

In its Response to the Secretary's Cross Motion for Summary Judgment, Medwin makes several new arguments. First, Medwin argues that the Secretary has interpreted LCD L26776 in such a way as to render meaningless, the provision setting the maximum limits per patient, per year, for tests 95903 and 95904. Dkt. No. 30 at 2-4. Medwin states that the Secretary's "argument is essentially that the only limit for CPT 95903 and 95904 is 2 tests per code for the diagnosis of sciatica." *Id.* at 3. Thus,

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[10] Medwin also refers to patient "D.B." to support its argument that the Secretary applies LCD L26776 in an inconsistent manner, though Medwin does not elaborate on how D.B's records support its argument. Dkt. No. 24 at 18.

by interpreting LCD L26776 so as to allow for only two tests per "code" for sciatica, Medwin claims that the Secretary has set the yearly limit at two tests per patient, per year for sciatica, instead of the actual eight tests per patient, per year for test 95903, and ten tests per patient, per year for test 95904. *Id*. Medwin asserts that this construction nullifies the portion of LCD L26776 which sets the annual limits for each test. *Id*. at 2-4. Medwin states that the Court should find that the Secretary's decision is arbitrary and capricious because it depends on an incorrect interpretation of LCD L26776. *Id*. Further, Medwin claims that the Secretary cannot justify its decision by arguing that substantial evidence supports it because Medicare's provisions are so voluminous and incoherent that it is clear the Secretary herself does not understand them. *Id*. at 1-2, 9.

Second, Medwin takes issue with the Secretary's summary judgment argument that Medwin failed to justify the testing it provided on a "single date of service." Dkt. No. 30 at 4 (quoting Dkt. No. 27 at 19). The Secretary's argument regarding testing provided on single dates of service is as follows:

> As noted by the Council, Plaintiff fails to acknowledge the per-study coverage criteria for NCS testing, let alone establish a nexus between the beneficiaries' clinical records and the relevant criteria. *See* AR 13. Plaintiff did not acknowledge or submit the Utilization Guidelines, *supra*, at 17, which establishes limits of the number of test deemed medically reasonable and necessary to evaluate certain diagnoses. AR 13. The Council further notes the LCD Utilization Guidelines are clear as to the maximum number of sites that may be billed to Medicare for the 95904 and 95903 codes on a particular date of service and diagnosis. *Id*.
>
> Conversely, in all of the statements of medical necessary provided by Plaintiff, as composed by Dr. Surya Raguthu, there is no mention of the LCD's per-study coverage criteria. *See generally* AR 1264, AR 1276, AR 1290, AR 1300, AR 1308, AR 1327. Dr. Raguthu provides no clinical

> explanation as to why additional testing sites were required for the studies at issue. *Id.* In fact, he does not mention the testing criteria at all in any of the statements of medical necessity. *Id.* Instead, Dr. Raguthu misstates the beneficiaries' NSC procedure codes were denied because "[the] documentation does not support care provided to patient." *Id.* Most notably, Dr. Raguthu's statements contain no justification for providing each beneficiary a year's worth of electrodiagnostic testing on a single date of service. *Id.*

Dkt. No. 27 at 18-19 (errors in original). In response to the Secretary's argument here, Medwin alleges as follows:

> The Secretary criticizes Dr. Ragthu's correspondence in one of the lower proceedings for allegedly containing, "no justification for providing each beneficiary **a year's worth of electrodiagnostic testing** on a single date of service." *Id.* at 18-19 (emphasis added). The Secretary is simply mistaken in her "year's worth of electrodiagnostic testing" assertion. Her record citation to "AR 1264, AR 1276, AR 1290, AR 1300, AR 1308, AR 1327" evidences correspondence related to 4 Sensory Nerves and 4 Motor Nerves. LCD 26776 provides in part, "Medicare will reimburse for the following numbers of tests **per year** per patient: . . . 95903 – eight/year[;] 95904 – ten/year . . ." *See* Defendant's Exhibit G, p.26 (Doc. No. 25-8) (emphasis added). Four is less than eight or ten. The Secretary's contention that four sensory and four nerve tests is "a year's worth of eltrodiagnostic testing" exemplifies the Secretary's arbitrary and capricious position of picking numbers at random.

Dkt. No. 30 at 4-5 (errors in original).

Third, Medwin elaborates upon its position that it performed bilateral testing on its six patients because it was medically necessary. Dkt. No. 30 at 5. It states that, "[t]esting only one nerve and then another is not how nerves are tested." *Id.* In support of this argument, Medwin relies upon "LCD L31346 issued by Wisconsin Physician Services[.]" *Id.* Among other things, Medwin states that LCD L31346 provides:

> Most nerves have a contralateral counterpart; **bilateral testing** is often necessary for comparison purposes. Nerves on each side may be billed separately. In addition, motor CPT code 95900 or 95903, sensory CPT

> code 95904, and mixed sensory CPT code 95904 studies on an individual nerve are appropriately carried out and billed separately.

Id. (emphasis in original).

Fourth, Medwin states that the language of LCD L26776 reveals that it is no substitute for the judgment of the treating, diagnosing physician. Dkt. No. 30 at 5-6. The LCD "provides exceptions for 'medically warranted' services based on a 'patient's medical record.'" *Id*. at 6 (quoting Dkt. No. 25-8, which contains LCD L26776 in its entirety).[11] Despite this, Medwin contends that the Secretary applies LCD L26776 as if "she and her underlings define the standard of care and the reasonableness and necessity of medical services with omniscient authority." *Id*. Medwin asserts that it provided medical records demonstrating the medical necessity of the additional tests. *Id*. It argues that the Secretary should not apply LCD L26776 "uniformly without regard to the clinical presentation of each unique patient." *Id*.

Fifth, Medwin argues that its physician, Dr. Raguthu, conducted additional tests for all six patients, in part, to help him rule out neuropathy, or differentiate between neuropathy and radiculopathy. Dkt. No. 30 at 6-7 (citing at AR 1278, 1284, 1295, 1300, 1310, 1327, 1329). Medwin states that LCD L26776 provides limits for diagnosing neuropathy, and that Medwin's tests did not exceed these limits. *Id*. at 7.

> According to LCD 26776, the "general limit" for diagnosing neuropathy is 4 tests for CPT 95904 and 2 tests for CPT 95903. *See* Defendant's Exhibit G, p.26 (Doc. No. 25-8). Thus, even under the Secretary's erroneous reading that LCD 72776's general limits provision provides the only limitation, Medwin was entitled to reimbursement for 4 tests per

[11] Medwin's cites Dkt. No. 25-8 as the exhibit containing LCD L26776. Dkt. No. 30 at 6. In this Report, however, the Court will refer to the exhibit containing LCD L26776 (*see* Dkt. No. 27-7), which is attached to the Secretary's live Cross Motion for Summary Judgment, rather than the exhibit (Dkt. 25-8) attached to her Motion to file Cross Motion for Summary Judgment in Excess of 20 pages.

> beneficiary for six beneficiaries under CPT 95904 regarding a diagnosis of or to rule out neuropathy.

Id. (errors in original). Thus, because its testing did not exceed the limits for radiculopathy and neuropathy testing, Medwin contends that the Secretary's decision denying payment for the tests is: (1) unsupported by substantial evidence; (2) unsupported by correct legal standards; and, (3) arbitrary and capricious. *Id*.

Sixth, Medwin argues that its nerve conduction testing ("NCS testing") was medically necessary.

> NCS testing is required for a clinical diagnosis of peripheral nervous system disorders. *See* for example AR 110. Additionally, for M.V. the patient had bilateral S.I. joint/ligament pain, (AR 000119), which made it appropriate and medically necessary to test two nerves bilaterally as opposed to one nerve bilaterally or two nerves unilaterally. For R. F. bilateral testing of two nerves was medically necessary as evidenced by the abnormal findings. AR 381. As explained, the intensity and extent of nerve testing is a matter of clinical judgment and are patient specific. AR 375. R.F's testing was medically necessary to evaluate her medical complaints. For E.P. the testing was medically necessary to determine proper medical treatment options. AR 553. For D.V. the testing was medically necessary to rule in or out failed back syndrome. AR 759. For J.A. and R.M. the testing was conducted to evaluate radiculopathy versus neuropathy and the patient had both. AR 921 and AR 1159. The medical records establish that all of the sensory testing was necessary for proper diagnosis and treatment.

Id. at 7-8 (errors in original).

Seventh, Medwin argues that it "had a good faith basis" for its billing "given the conflict between Medicare's determination and conflicting LCDs." Dkt. No. 30 at 8. Medwin contends that the governing provisions of Medicare also lack clarity. *Id*. at 8-9. Because of this, Medwin suggests that it should be considered "'without fault' for any overpayment" pursuant to 42 U.S.C.

§ 1395gg(b). Dkt. No. 1 at ¶ 34. In support of this argument, Medwin contends as follows:

> According to Medicare national Coverage Determination Manual, Chapter 1, Part 2, Section 160.23 – Sensory Nerve Conduction Threshold Test (sNCTs) (Effective April 1, 2004), attached as Exhibit #, p. 82-83, "All uses of sNCT to diagnose sensory neuropathies or radiculopathies are noncovered." But then, there is LCD 26776, effective for services performed on or about January 1, 2012. *See* Defendant's Exhibit G, p.2 (Doc. No. 25-8). There is also LCD L31346, which recognizes the need for bilateral testing and 3 motor tests and 2 sensory tests for the diagnosis of radiculopathy. *See* Exhibit 1. The differences between LCD 26776 and L31346 evidence a level of subjectivity in arriving at testing limits. Accordingly, Medwin had a good faith belief that its testing was in accordance with LCD 26776 because it was well documented and within the ***real*** maximum limits.

Id. (errors and emphasis in original). Medwin adds that the Secretary cannot correctly argue that the Council had substantial evidence to make a determination about Medwin's good faith by assessing its credibility because "there was no in-person hearing to access demeanor." *Id*. at 8 (errors in original).

IV. Discussion

At the threshold, the Court notes that the parties have devoted a significant amount of briefing in this case to arguing over whether Medwin should be allowed to "complete" or "supplement" the administrative record with evidence unrelated to the six patients at issue here (hereinafter referred to as the "contested evidence"). *See* Dkt. No. 16, Dkt. No. 18, Dkt. No. 24 at 16-19, Dkt. No. 31 at 1-8, Dkt. No. 32 at 5-10, Dkt. No. 33 at 1-8. The Court summarized Medwin's arguments regarding this issue briefly above, but finds no need to summarize the parties' arguments in more detail. As will be shown below, even assuming that Medwin may rely on the contested

evidence, a review of the contested evidence reveals that Medwin is not entitled to relief.[12]

Contrary to Medwin's claims, the contested evidence does not support Medwin's contention that the Council applied legal standards randomly or incorrectly, nor does it show that the Secretary's decision is unsupported by substantial evidence. As the Secretary notes, her disposition of other claims is irrelevant because each Medicare claim presents different evidence. Dkt. No. 31 at 7. Therefore, even if two or more patients are evaluated for the same condition and receive the same number and type of tests, this fact alone is not dispositive. Dkt. No. 18 at 4.

> Each claim stands on its own merits as to whether it should be allowed or denied based on the evidence found within the medical records used to substantiate that specific claim. Whether to allow or deny a claim turns on the specific facts surrounding the claim. The allowance of a claim under one set of facts does not become a blanket approval for every other claim submitted for the same service under a different set of facts. Every claim must be judged on its own merits.

Id.

Here, the contested evidence Medwin relies upon is found in an exhibit attached to its Motion for Summary Judgment. Dkt. No. 24-1 ("Exhibit 1"). This exhibit contains records for "M.G." *Id.* Again, with respect to these records, Medwin states:

> [Medwin] refers to the appeal relating to M.G. AR 001208 and 001213. The claim was originally denied by Novitas, but the Qualified Independent Contractor, Q2 Administrators, determined that the claim was not overpaid. *See* Exhibit 1. Furthermore, the QIC determined that the LCD requirements had been met. *Id.* That same QIC *denied claims for the same testing and for the same indication* in the appeals made the basis of this lawsuit. The decision to deny claims after having

[12] The Court notes here that it is not finding that Medwin has the right to submit the contested evidence, it is merely finding that the contested evidence is immaterial because it does not alter the Court's conclusion that Medwin has failed to show an entitlement to relief.

> determined *similar* claims are payable is an abuse of discretion, arbitrary and capricious.

Id. at 16 (errors in original, emphasis added). *See also* Dkt. No. 32 (making the same argument, but referring to the patient inconsistently as "M.D." and "M.G.").

The flaw in Medwin's argument here is that it fails to account for the fact that M.G.'s medical records are not materially identical to the medical records of the six patients at issue in this case. *Compare* Dkt. No. 24-1 at 1-2, *with* AR at 1264-1282, 1288-1233. Similarly, Medwin has not shown that the two patients whose claims were paid had records materially identical to the six patients at issue here. This matters because two patients may receive the exact same tests for the exact same indication, but one patient's medical records may show that the testing was medically reasonable and necessary, whereas the other patients' records may not. Medwin has not demonstrated that the six patients claims were denied, whereas other claims were approved, based upon materially identical facts. By asking the Court to reverse the Secretary's decision, Medwin is asking the Court to reweigh the evidence and substitute its judgment for that of the Secretary. The Court cannot accede to Medwin's request and still follow the well-established authority of this Circuit. *See Hollis v. Bowen*, 837 F.2d 1378, 1383 (noting that the reviewing court "may neither reweigh the evidence in the record nor substitute [its own] judgment for the Secretary's.") (citing *Neal v. Bowen*, 829 F.2d 528, 530 (5th Cir. 1987)).

The above-discussed flaw in Medwin's argument pervades its briefing. Again, Medwin argues that the six patients at issue here were all being evaluated for the same condition, radiculopathy. Dkt. No. 24 at 15. Despite this, for four patients, "the

Agency determined that 3 motor nerves should be tested[,]" while for "one of the patients the Agency determined that 4 motor nerves should be tested." *Id.* Medwin insists that this constitutes evidence that the Secretary's decision is unsupported by correct legal standards and substantial evidence. *Id.* at 19. Additionally, Medwin argues that this constitutes evidence that the Secretary applies legal standards arbitrarily and capriciously. *Id.* Here again, however, Medwin has failed to eliminate the possibility that differences in each patient's medical records explain the differences in coverage.

The flaws in Medwin's remaining arguments are similarly fatal to its Motion for Summary Judgment. Medwin argues that the Secretary has interpreted LCD L26776 in such a way as to render meaningless, the provision setting the maximum limits per patient, per year, for tests 95903 and 95904. This argument is not supported by the record. In its decision, the Council specifically noted that, despite the yearly maximums, Medwin still had to justify its testing per diagnosis on a particular date of service. AR at 13. As the Council stated:

> The Council does not find that [Medwin] has adequately documented the need for testing additional sites greater than the numbers indicated in the Utilization Chart attached to LCD L26776. . . . The attachment to the LCD is clear, however, as to the maximum number of sites that may be billed to Medicare for the 95904 and 95903 codes *on a particular date of service and diagnosis*. In each instance, for a diagnosis of sciatica, [Medwin] exceeded the maximum number of tests needed to diagnose each beneficiary's condition. *See* LCD L26776. The medical records provided by [Medwin] *do not explain why* the additional testing was medically necessary. Exh. MAC-3.

Id. (emphasis added). Requiring Medwin to justify additional testing per diagnosis, does not amount to a nullification of LCD L26776's provision setting the maximum

yearly limits for tests 95903 and 95904. A patient could, for example, be tested numerous times throughout a year without exceeding LCD L26776's yearly or per diagnosis testing limits. Conversely, a patient could exceed LCD L26776's per diagnosis testing limits on a particular date of service, without exceeding LCD L26776's yearly limits for the same tests. In yet a third scenario, a patient could exceed LCD L26776's yearly testing limits, while not exceeding LCD L26776's limits for a diagnosis on a particular date of service. Medwin's argument is logically flawed and does not demonstrate that the Secretary's decision is unsupported by correct legal standards or substantial evidence.

Medwin also attacks the Secretary's "year's worth of electrodiagnostic testing on a single date of service" argument. Dkt. No. 30 at 4-5. Again, in its Cross Motion for Summary Judgment, Medwin states:

> The Secretary criticizes Dr. Ragthu's correspondence in one of the lower proceedings for allegedly containing, "no justification for providing each beneficiary **a year's worth of electrodiagnostic testing** on a single date of service." *Id*. at 18-19 (emphasis added). The Secretary is simply mistaken in her "year's worth of electrodiagnostic testing" assertion. Her record citation to "AR 1264, AR 1276, AR 1290, AR 1300, AR 1308, AR 1327" evidences correspondence related to 4 Sensory Nerves and 4 Motor Nerves. LCD 26776 provides in part, "Medicare will reimburse for the following numbers of tests **per year** per patient: . . . 95903 – eight/year[;] 95904 – ten/year . . ." *See* Defendant's Exhibit G, p.26 (Doc. No. 25-8) (emphasis added). Four is less than eight or ten. The Secretary's contention that four sensory and four nerve tests is "a year's worth of eltrodiagnostic testing" exemplifies the Secretary's arbitrary and capricious position of picking numbers at random.

Dkt. No. 30 at 4-5 (errors in original).

In the Secretary's "Reply to Plaintiff's Response in Opposition to Defendant's Motion for Summary Judgment" (hereinafter, the Secretary's "Reply"), the Secretary

acknowledges that its Cross Motion for Summary Judgment contains an error. Dkt. No. 33 at 6, note 4 (referring to Dkt. No. 27 at 19). Specifically, the Secretary notes that her reference to "a year's worth of electrodiagnostic testing on a single date of service" was a "misstatement." *Id*. Nevertheless, the Secretary's underlying argument is not dependent on its misstatement. The gravamen of the Secretary's argument is that, before the Council, Medwin failed to explain why additional testing was done, per diagnosis on a single date of service, beyond that permitted by LCD L26776. *See* Dkt. No. 27 at 18-19.

Medwin argues that it provided statements of medical necessity to the Council for each of its six patients, and that these statements demonstrate that the additional testing was, in fact, medically justified. Dkt. No 30 at 5-8. The statements Medwin is referring to, however, do not explain why the additional testing was done, per diagnosis on single dates of service, beyond that permitted by LCD L26776. *See* AR 1264, 1276, 1290, 1300, 1308, 1327. Instead, the statements of medical necessity for each of the six patients all make general statements regarding the appropriateness and necessity of the testing. *Id*. In addition, these statements each provide as follows:

> As mentioned procedure codes 95900 (4 units), 95903 (4 units) & 95904 (2 units) which have been denied stating documentation does not support care provided to patient. I request you to review medical records again (find attached progress notes for Electromyography) and where following nerves have been tested.

Id. (errors in original).

Rather than providing an individual explanation as to why each patient required additional testing per diagnosis, then, the statements of medical necessity merely implore the Council to look at each patient's medical records again. AR 1264,

1276, 1290, 1300, 1308, 1327. As the Council and the parties correctly note,[13] these records were already a part of the record, and had already been reviewed by the Agency. *See* AR at 108-122, 373-385, 543-556, 749-762, 914-925, 1151-1163.

The Secretary argues that Medicare providers bear the burden of demonstrating medical necessity and entitlement to payment. Dkt. No. 27 at 15. The Secretary is correct. *See Clinic Res. Mgmt. v. Burwell*, Civil Action No. H-14-578, 2015 WL 3932657, at *2 (S.D. Tex. June 26, 2015) (citing "42 U.S.C. § 13951(e); 42 C.F.R. § 424.5(a)(6); *Friedman v. Sec'y of Dep't of Health and Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987)"). Before the Council, Medwin failed to explain why the additional testing was done for its six patients, per diagnosis on single dates of service, beyond that permitted by LCD L26776. AR at 1262-1333. Further, prior to the Council's review, Medwin had not provided the Agency with an explanation as to why the additional testing was done for its six patients, per diagnosis on single dates of service, beyond that permitted by LCD L26776. *See* AR at 108-122, 373-385, 543-556, 749-762, 914-925, 1151-1163. Instead, Medwin provided more general justifications for its testing — stating, for instance, that its testing was justified as a matter of clinical judgment. *Id.* at 110, 375, 545, 751, 917, 1153.

Accordingly, the Council's conclusion, that Medwin failed to explain the additional testing (*see* AR at 12-13), is supported by correct legal standards and substantial evidence. *See* AR at 108-122, 373-385, 543-556, 749-762, 914-925, 1151-

[13] AR at 12 (containing the Council's reference to the records as records "previously sent to the QIC"); *Id.* at 1263, 1275, 1289, 1299, 1307, 1326 (containing Medwin's statement that the medical records were previously provided in the prior appeal" and were "not new evidence") (emphasis in original); Dkt. No. 27 at 15 (containing the Secretary's reference to the records as "previously submitted medical records").

1163, 1262-1333; 42 C.F.R. § 424.5(a)(6) (stating that Medicare providers bear the burden of demonstrating medical necessity and entitlement to payment); *Clinic Res. Mgmt. v. Burwell*, Civil Action No. H-14-578, 2015 WL 3932657, at *2 (same). The Secretary has, therefore, met her burden under Rule 56 and is entitled to summary judgment.

Medwin cannot remedy its failure before the Council now, by attempting to introduce new arguments to the Court to explain the medical necessity of the additional tests. "A reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented and deprives the [agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action." *Unemployment Comp. Comm'n of Alaska v. Aragon*, 329 U.S. 143, 155 (1946); *W. Virginia Dep't of Health & Human Res. v. Sebelius*, 709 F. Supp. 2d 487, 493 (S.D. W. Va. 2010), *aff'd*, 649 F.3d 217 (4th Cir. 2011) (same).

> In reviewing an administrative-agency decision, a court should not consider arguments that were not raised before the agency. This is particularly true when the issue raised would require fact-finding by the agency and in cases where "the Secretary's expertise is relevant" to a resolution of the issue. *Pleasant Valley Hosp., Inc. v. Shalala*, 32 F.3d 67, 70 (4th Cir. 1994); *see also Delta Foundation, Inc. v. United States*, 303 F.3d 551, 560 (5th Cir. 2002) ("The rationale for requiring issue exhaustion is that parties should have an opportunity to offer evidence before the administrative agency charged with the fact finding responsibility.").

W. Virginia Dep't of Health & Human Res. v. Sebelius, 709 F. Supp. 2d 487, 493.

Here, several of Medwin's arguments before the Court constitute new arguments of medical necessity that were not presented to the Council. For example, Medwin argues that the additional tests per diagnosis were necessary to help Dr.

Raguthu rule out neuropathy, or differentiate between neuropathy and radiculopathy. Dkt. No. 30 at 6-7. This may be true. Four of the letters of medical necessity Dr. Raguthu provided mentioned neuropathy in addition to radiculopathy. AR at 1276, 1300, 1308, 1327. Most of the six patients' medical records contained some mention of radiculopathy and neuropathy. *See, e.g., id.* at 1278, 1295, 1305, 1310, 1321, 1329. Finally, the medical records for R.F., J.A. and R.M. state that the "EMG & nerve conductions are done to rule out radiculopathy versus peripheral neuropathy." *Id.* at 1278, 1310, 1329. Nevertheless, there is no evidence in the record that Medwin argued, before the Council, that the additional tests were necessary, per diagnosis on particular dates of service, to help Dr. Raguthu rule out neuropathy, or differentiate between neuropathy and radiculopathy. Moreover, the record reveals that Medwin never presented the Agency with the evidence showing that the additional tests per diagnosis were necessary to help Dr. Raguthu rule out neuropathy, or differentiate between neuropathy and radiculopathy.

In appealing the QIC's decisions to the Council, Medwin provided six statements of medical necessity. AR 1264, 1276, 1290, 1300, 1308, 1327. These statements of medical necessity implored the Council to look at the patients' medical records again. *Id.* But, these statements did not explain that the additional tests were necessary to help Dr. Raguthu rule out neuropathy, or differentiate between neuropathy and radiculopathy. *Id.* As already noted above, these statements provided no explanation as to why additional testing was done, per diagnosis on a single date of service, beyond that permitted by LCD L26776. *Id.* This is critical because, as the Council pointed out in its decision, the QIC explicitly denied payment

due to Medwin's failure to explain "the numbers of sites tested, on a particular date of service, for a specific diagnosis." *Id.* at 13. Having failed to correct this same deficiency before the Council, then, the Council adopted the QIC's decision. *See id.* (noting that Medwin failed to "explain why the additional testing was medically necessary."). Medwin has not shown that the Council's decision was unsupported by substantial evidence or correct legal standards.

Medwin's other new medical necessity arguments fail for the same reason. Medwin contends that the additional testing was justified because bilateral testing was medically necessary. Dkt. No. 30 at 5. Medwin also asserts that its NCS testing was medically necessary to diagnose other conditions such as "failed back syndrome." *Id.* at 8. Medwin did not present these arguments to the Council to explain why additional testing was done, per diagnosis on a single date of service, beyond that permitted by LCD L26776. Accordingly, the Court may not use Medwin's new arguments to reverse the Secretary's decision. *See Unemployment Comp. Comm'n of Alaska v. Aragon*, 329 U.S. 143, 155 ("A reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented and deprives the [agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action."); W. *Virginia Dep't of Health & Human Res. v. Sebelius*, 709 F. Supp. 2d 487, 493 ("In reviewing an administrative-agency decision, a court should not consider arguments that were not raised before the agency. This is particularly true when the issue raised would require fact-finding by

the agency and in cases where "the Secretary's expertise is relevant" to a resolution of the issue.") (citations omitted).[14]

Next, Medwin states that it "had a good faith basis" for its billing "given the conflict between Medicare's determination and conflicting LCDs." Dkt. No. 30 at 8. Medwin contends that the governing provisions of Medicare also lack clarity. *Id*. at 8-9. Because of this, Medwin suggests that it should be considered "'without fault' for any overpayment" pursuant to 42 U.S.C. § 1395gg(b). Dkt. No. 1 at ¶ 34. There is, however, no evidence that Medwin made this argument before the Council. The Council's decision also indicates that Medwin did not raise this argument. AR at 13. Citing 42 C.F.R. § 405.1112(c), the Council stated that it would adopt "the QIC's findings regarding liability without further discussion[,]" as Medwin had "not raised any exceptions before the Council regarding its liability[.]" *Id*. Section 405.1112(c) provides that the Council "will limit its review of an ALJ's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary." 42 C.F.R. § 405.1112(c); *see also Momentum EMS, Inc. v. Sebelius*, No. 4:11-CV-298, 2014 WL 199061, at *12–13 (S.D. Tex. Jan. 13, 2014) (noting that, pursuant to 42 CFR § 405.1112(c), the scope of the Council's review is limited to "those exceptions raised by the party in the request for review"). Medwin was not unrepresented before the Council. *See* AR at 1261. Thus, having failed to show that it raised the issue of its lack of fault before the Council, Medwin has not shown that the Council erred in failing to consider its lack of fault under 42 U.S.C. § 1395gg(b).

[14] In support of its argument that bilateral testing was medically necessary, Medwin also relies upon "LCD L31346 issued by Wisconsin Physician Services[.]" Dkt. No. 30 at 5. As the Secretary correctly points out, however, LCD L31346 does not apply in Texas. *See* Dkt. No. 33 at 8; Dkt. No. 33-2 at 2-5.

Relatedly, Medwin may not raise the issue now because it did not raise the issue before the Council. *See Unemployment Comp. Comm'n of Alaska v. Aragon*, 329 U.S. 143, 155; *W. Virginia Dep't of Health & Human Res. v. Sebelius*, 709 F. Supp. 2d 487, 493.[15]

Medwin also contends that the Secretary cannot correctly argue that the Council had substantial evidence to make a determination about Medwin's good faith in billing by assessing its credibility because "there was no in-person hearing to access demeanor." Dkt. No. 30 at 8 (errors in original). It is true that no in-person hearing occurred. *See* AR at 2-14. But, it is also true that the Council did not base its decision on Medwin's credibility, or make any findings about Medwin's credibility. *Id*. Therefore, Medwin's argument here does highlight a poor choice of words in the Secretary's briefing before this Court. *See* Dkt. No. 27 at 22 ("[T]he Council found, based upon the substantial evidence, that Plaintiff was not credible in asserting that it had a reasonable basis for believing that Medicare payment for the electrodiagnostic services was proper."). Medwin's argument, however, does not expose an error in the Secretary's final decision.

Medwin's remaining arguments contain numerous critiques of the Secretary's decision and Medicare's provisions. As summarized more fully above, Medwin claims that: (1) the Secretary applies LCD L26776 as if "she and her underlings define the standard of care and the reasonableness and necessity of medical services with

[15] The Secretary argues that Medwin's assertions about its lack of fault in billing are also incorrect. *See* Dkt. No. 27 at 7-8, 19-22. The Court has reviewed the Secretary's arguments and finds them to be largely correct. Though, as noted above, the Court need not substantively address Medwin's arguments concerning its fault because, in addition to being insufficiently briefed, Medwin's arguments were not presented to the Council.

omniscient authority[;]" (2) in applying LCD L26776 this way, the Secretary has invaded the province of the treating/diagnosing physician and disregarded each patient's medical records and clinical presentation; (3) the Secretary does not understand Medicare's provisions, and the provisions lack clarity; and, (4) due to this lack of understanding and clarity, the Secretary's application of Medicare's provisions was arbitrary and capricious, legally incorrect, and unsupported by substantial evidence. Dkt. No. 30 at 1-2, 4-6, 8-9.

Medwin has provided no authority to transform these general criticisms into arguments entitling it to relief. The Court's role is limited to two inquiries: (1) determining whether the Secretary applied the correct legal standards; and (2) determining whether there is substantial evidence in the record to support the Secretary's decision. *Estate of Morris v. Shalala*, 207 F.3d 744, 745. Medwin has not identified any legal errors in the Secretary's decision, nor has it shown that substantial evidence fails to support her decision. Moreover, for the reasons provided above, the Secretary's decision is supported by correct legal standards and substantial evidence. It is, therefore, recommended that the Court: (1) grant the Secretary's Cross Motion for Summary Judgment; (2) deny Medwin's Motion for Summary Judgment; and, (3) dismiss this civil action with prejudice.

V. Recommendation

For the foregoing reasons, it is recommended that the Court: (1) grant the Secretary's Cross Motion for Summary Judgment; (2) deny Medwin's Motion for Summary Judgment; and, (3) dismiss this civil action with prejudice.

VI. Notice to Parties

A party's failure to file written objections to the proposed findings, conclusions, and recommendation in a magistrate judge's report and recommendation within fourteen days after being served with a copy shall bar that party, except upon grounds of plain error, from attacking on appeal the unobjected-to proposed factual findings and legal conclusions accepted by the district court, provided that the party has been served with notice that such consequences will result from a failure to object. *Douglass v. United Services Auto. Ass'n*, 79 F.3d 1415 (5th Cir. 1996).

Signed on this 31st day of January, 2017.

Ignacio Torteya, III
United States Magistrate Judge